Edwards Lifesciences

510(k) Summary

A. Submitter Information

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614-5686, USA

Contact: Kevin Drisko, Senior Manager Regulatory Affairs
Phone Number: (949) 250-2416
Fax Number: (949) 250-3630
Email address: kevin_drisko@edwards.com

B. Device Information

1. Trade Name:
   Edwards Directional Catheter

2. Common or Usual Name:
   Percutaneous Catheter

3. Device Classification and Classification Name:
   Class II (74 DQY, 21 CFR §870.1250)

4. Predicate Device Identification:
   BioCardia Universal Deflectable Guide Catheter (K012749)
   Cardima Naviport Deflectable Guide Catheter (K974683)

5. Device Description:
   The Edwards Directional Catheter is 99 cm in length and 16F outer diameter. The body has two lumens, one for a deflectable spring, and the other to allow it to track on a 0.035" guidewire. The sheath on the subject device provides a smooth transition from the body to the tip of the catheter. The tip of the catheter is made from a soft material that offers flexibility. The body of the catheter is made from a higher durometer material that offers better torqueability. When the sheath of the device is retracted, the spring tip can be deflected using the knob located at the proximal end. The spring tip can be adjusted from approximately 0° to 180° by sliding the knob back and forth. There is also a port that allows a 0.035" guidewire to pass through the catheter and exit through the deflecting tip.

6. Intended Use:
   The Edwards Directional Catheter is indicated to facilitate the placement of guidewires in bifurcations or any sidebranch vasculature.

7. Technological Comparison of Subject Device to Predicate Device:
The Edwards Directional Catheter is similar to the predicate devices in that all three provide access to the vasculature and facilitate the placement of guidewires, interventional devices, or therapeutic and diagnostic devices. Similar materials are used in each to enhance maneuverability of the devices and to prevent damage to vessels.

8. Summary of Non-Clinical Tests and Conclusions:
The following non-clinical testing was performed on the Edwards Directional Catheter:
- Biocompatibility testing/chemical acceptability testing
- Physical and mechanical specification testing
- Sterilization testing
- Animal Studies

Based on the results of this testing, Edwards Lifesciences has determined that the Edwards Directional Catheter is acceptable in design and construction for its intended use.

9. Summary of Clinical Tests and Conclusions:
Clinical testing was not deemed necessary to establish the substantial equivalence of the subject device to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2003

Edwards Lifesciences LLC
c/o Kevin Drisko
Senior Manager Regulatory Affairs
One Edwards Way
Irvine, CA 92614-5686

Re: K030630
Percutaneous Catheter
Regulation Number: 870.1250
Regulation Name: Catheter percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: June 24, 2003
Received: June 25, 2003

Dear Mr. Drisko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

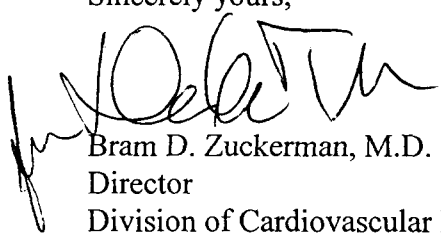
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications For Use

510(k) Number (if known): K030630

Device Name: Edwards Directional Catheter

Indications for Use:

The Edwards Directional Catheter is indicated to facilitate the placement of guidewires in bifurcations or any sidebranch vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030630

Prescription Use X OR Over-The-Counter Use ____
(per 21 CFR 801.109)